

Chapter 8 Gas Equipment

8-1* Scope.

8-1.1 This chapter covers the performance, maintenance, and testing of gas equipment used within health care facilities.

8-1.2* This chapter applies to the use of nonflammable medical gases, vapors, and aerosols, and the equipment required for their administration, at normal atmospheric pressure.

8-1.3 When used in this chapter, the term *oxygen* is intended to mean 100 percent oxygen as well as mixtures of oxygen and air.

8-1.4* This chapter does not apply to special atmospheres, such as those encountered in hyperbaric chambers.

8-2* Nature of Hazards.

8-2.1 Fire and Explosions.

8-2.1.1 Inhalation Anesthetizing Locations.

8-2.1.1.1 Oxygen and nitrous oxide, the gases normally used for relative analgesia and as components of general anesthesia, are strong oxidizing gases and individually or as a mixture support combustion quite readily.

8-2.1.1.2 Inhalation gases or vapors introduce fire, chemical, mechanical, and electrical hazards that are all interrelated. Any mixture of inhalation gases will support combustion. In an oxygen-enriched atmosphere, materials that are flammable and combustible in air ignite more easily and burn more vigorously. The materials that could be found on or near patients include hair oils, oil-based lubricants, skin lotions, clothing, linens, paper, rubber, alcohols, acetone, and some plastics.

8-2.1.1.3 A hazard exists if any of the components of an oxygen or nitrous oxide supply system become contaminated with oil or grease.

8-2.1.1.4* Sources of ignition can include open flames, burning tobacco, electric heating coils, defective electrical equipment, and adiabatic heating of gases.

8-2.1.1.5 A hazard exists if either oxygen or nitrous oxide leaks into a closed space, creating an oxygen-enriched atmosphere.

8-2.1.1.6 A hazard exists if improper components are employed to connect equipment containing pressurized oxygen or nitrous oxide.

8-2.1.2 During Respiratory Therapy Administration.

8-2.1.2.1 The occurrence of a fire requires the presence of combustible or flammable materials, an atmosphere of oxygen or other oxidizing agents, and a source of ignition. Combustible materials can be unavoidably present when oxygen is being administered, but flammable liquids and gases and ignition sources are avoidable.

Any mixture of breathing gases used in respiratory therapy will support combustion. In an oxygen-enriched atmosphere, materials that are combustible and flammable in air ignite more easily and burn more vigorously. Materials not normally considered to be combustible may be so in an oxygen-enriched atmosphere.

8-2.1.2.2 Combustible materials that could be found near patients who are to receive respiratory therapy include hair oils, oil-based lubricants, skin lotions, facial tissues, clothing,

bed linen, tent canopies, rubber and plastic articles, gas-supply and suction tubing, ether, alcohols, and acetone.

8-2.1.2.3 A particular hazard exists when oxygen equipment becomes contaminated with oil, grease, or other combustible materials. Such contaminants will ignite readily and burn more rapidly in the presence of high oxygen concentrations and make it easier to ignite less combustible materials with which they come in contact.

An oxygen-enriched atmosphere normally exists in an oxygen tent, croup tent, incubator, and similar devices when supplemental oxygen is being employed in them. These devices are designed to maintain a concentration of oxygen higher than that found in the atmosphere.

Oxygen-enriched atmospheres can exist in the immediate vicinity of all oxygen administration equipment. (*See definition of Site of Intentional Expulsion in Section 2-2.*)

The transfer of liquid oxygen from one container to another container can create an oxygen-enriched atmosphere within the vicinity of the containers.

If oxygen is supplied by a container that stores the oxygen as a liquid, there will be a small amount of oxygen vented into the vicinity of the container after a period of nonuse of the equipment. Larger amounts of oxygen will be vented if the container is accidentally tipped over or placed on its side. This venting may create an oxygen-enriched atmosphere if the container is stored in a confined space [*see 4-3.1.1.2(a)9*].

8-2.1.2.4 Sources of ignition include not only the usual ones in ordinary atmospheres, but others that become significant hazards in oxygen-enriched atmospheres (*see 8-2.1.2.1*) such as the following:

(a) Open flames, burning tobacco, and electric radiant heaters are sources of ignition.

(b) The discharge of a cardiac defibrillator can serve as a source of ignition.

(c) Arcing and excessive temperatures in electrical equipment are sources of ignition. Electrically powered oxygen apparatus and electrical equipment intended for use in an oxygen-enriched atmosphere are sources of ignition if electrical defects are present.

(d) Electrical equipment not conforming to the requirements of 7-6.2.4.1, which can include, but is not limited to, electric razors, electric bed controls, hair dryers, remote television controls, and telephone handsets, can create a source of ignition if introduced into an oxygen-enriched atmosphere (*see 7-6.2.4.1*).

(e) A static discharge having an energy content that can be generated under normal conditions in respiratory therapy will not constitute an ignition source as long as easily ignited substances (such as alcohols, acetone, oils, greases, or lotions) are not present.

(f) Rapid opening of cylinder valves can cause sudden increase in downstream gas pressure and temperature caused by the adiabatic heat of recompression with consequent ignition of combustible materials in contact with the hot gas downstream, including the valve seat.

8-2.2 Toxicity.

8-2.2.1 During Respiratory Therapy Administration.

8-2.2.1.1 Chemical hazards can be associated with the presence of residual sterilant in high-pressure equipment.

8-2.2.1.2 Some breathing mixtures can decompose in contact with hot surfaces and produce toxic or flammable substances (see 8-6.2).

8-2.2.1.3 Smoldering combustion of flammable substances can occur with the production of significant amounts of toxic gases and fumes.

8-2.3 Safety (Mechanical Injury; Cross-Connection, and So Forth).

8-2.3.1 Inhalation Anesthetizing Locations. A large amount of energy is stored in a cylinder of compressed gas. If the valve of a cylinder is struck (or strikes something else) hard enough to break off the valve, the contents of the cylinder could be discharged with sufficient force to impart dangerous reactive movement to the cylinder.

8-2.3.2 During Respiratory Therapy Administration.

8-2.3.2.1 Mechanical Hazards. Cylinders and containers can be heavy and bulky and can cause personal injury or property damage (including to the cylinder or container) if improperly handled. In cold climates, cylinders or containers stored outdoors or in unheated ventilated rooms can become extremely cold [see 4-3.5.2.1(b)30 and 4-3.5.2.1(b)31]. A hazardous situation could develop if these cylinders or containers are heated [see 4-3.5.2.1(b)29].

8-2.3.2.2 Improper maintenance, handling, or assembly of equipment can result in personal injury, property damage, or fire.

8-2.3.2.3 A hazardous condition exists if cylinders or containers are improperly located so that they can become overheated or tipped over. If a container is tipped over or placed on its side, liquid oxygen could be spilled. The liquid can cause frostbite on contact with skin.

8-2.3.2.4 A hazardous condition exists if there is improper labeling of cylinders or containers or inattention to the manufacturer's label or instructions.

8-2.3.2.5 A hazardous condition exists if care is not exercised in making slip-on and other interchangeable connections when setting up equipment.

8-2.3.2.6 Safety features, including relief devices, valves, and connections, are provided in equipment and gas supply systems. Altering or circumventing these safety features by means of adapters creates a hazardous condition.

8-2.3.2.7 Extreme danger to life and property can result when compressed gases are mixed or transferred from one cylinder to another.

8-2.3.2.8 A hazardous condition exists if devices, such as fixed or adjustable orifices and metering valves, are directly connected to cylinders or systems without a pressure-reducing regulator.

8-2.3.2.9 Hazardous conditions are created when pressure-reducing regulators or gauges are defective.

8-2.4* Electric Shock. (Reserved)

8-3 Source.

8-3.1 Cylinders and Containers.

8-3.1.1 Cylinders and containers shall comply with 4-3.1.1.1(a).

8-3.1.2 Cylinder valve outlet connections shall conform to CGA V-1, *Standard for Compressed Gas Cylinder Valve Outlet and*

Inlet Connections (ANSI B57.1) (includes Pin-Index Safety System for medical gases). [See 4-3.1.1.1(a).]

8-3.1.3 When low-pressure threaded connections are employed, they shall be in accordance with the Compressed Gas Association standard for noninterchangeable, low-pressure connections for medical gases, air, and suction, CGA Pamphlet V-5, *Diameter-Index Safety System*.

8-3.1.4 Low-pressure quick-coupler connections shall be noninterchangeable between gas services.

8-3.1.5 Regulators and gauges intended for use in high-pressure service shall be listed for such service.

8-3.1.6 Pressure-reducing regulators shall be used on high-pressure cylinders to reduce the pressure to working pressures.

8-3.1.7 Approved regulators or other gas-flow control devices shall be used to reduce the cylinder pressure of every cylinder used for medical purposes. All such devices shall have connections so designed that they attach only to cylinders of gas for which they are designated.

8-3.1.8* Equipment that will permit the intermixing of different gases, either through defects in the mechanism or through error in manipulation in any portion of the high-pressure side of any system in which these gases might flow, shall not be used for coupling cylinders containing compressed gases.

8-3.1.9 Cylinder valve outlet connections for oxygen shall be Connection No. 540 as described in CGA V-1, *Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections* (ANSI B57.1).

8-3.1.10 Cylinder valve outlet connections for nitrous oxide shall be Connection No. 326 as described in CGA V-1, *Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections* (ANSI B57.1).

8-3.1.11 Storage Requirements.

8-3.1.11.1 Storage for nonflammable gases greater than 3000 ft³ (85 m³) shall comply with 4-3.1.1.2 and 4-3.5.2.2.

8-3.1.11.2 Storage for nonflammable gases less than 3000 ft³ (85 m³).

(a) Storage locations shall be outdoors in an enclosure or within an enclosed interior space of noncombustible or limited-combustible construction, with doors (or gates outdoors) that can be secured against unauthorized entry.

(b) Oxidizing gases, such as oxygen and nitrous oxide, shall not be stored with any flammable gas, liquid, or vapor.

(c) Oxidizing gases such as oxygen and nitrous oxide shall be separated from combustibles or incompatible materials by either:

1. A minimum distance of 20 ft (6.1 m), or
2. A minimum distance of 5 ft (1.5 m) if the entire storage location is protected by an automatic sprinkler system designed in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems*, or
3. An enclosed cabinet of noncombustible construction having a minimum fire protection rating of one-half hour for cylinder storage. An approved flammable liquid storage cabinet shall be permitted to be used for cylinder storage.

(d) Liquefied gas container storage shall comply with 4-3.1.1.2(b)4.

9-2.1.6.4 Electromagnetic Compatibility. All appliances shall be designed so that they are capable of operating in a radio frequency electromagnetic environment where limits are established by IEC 60601-1-2.

9-2.1.6.5 Operation with Essential Electrical System.

(a) *General.* Equipment (fixed or appliances) shall be designed to operate normally when energized by a standby power source that conforms to the requirements of Chapter 3.

(b) *Power Transfer.* Following transfer of power between the normal power system and the essential electrical system, a patient-care-related appliance shall resume function in the mode of operation that existed prior to the transfer.

Exception: If the appliance cannot maintain its mode of operation in the event of a power transfer, it shall default to a nonhazardous status and clearly indicate by audible or visible signals that its mode of operation has changed.

(c) *Programmable Appliances.* Deenergization of the power supply of a programmable appliance shall not result in the loss or change of any part of the program or data required for normal operation.

Exception No. 1: This requirement does not apply to computers and programmable appliances that are not directly related to patient care.

Exception No. 2: Patient-care-related appliances that could suffer loss of program or vital data shall default to a start-up status and clearly indicate by audible or visual signals that its program or data has been altered or lost.

9-2.1.7 Fire and Explosion Hazards.

9-2.1.7.1 Materials and Supplies. Materials used in the construction of, and supplies for, electric appliances shall be non-combustible or flame retardant and impermeable to liquids and gases to the extent practicable; or the materials used in the construction of, and supplies for, electric appliances shall not ignite from internal heating or arcing resulting from any and all possible fault conditions. This includes spillage of liquids such as water and intravenous solutions onto the appliance.

Exception: Materials used in the construction and operation of electric appliances shall be permitted to be combustible when it is essential to their intended function.

9-2.1.7.2* Oxygen-Enriched Atmospheres. Electric appliances employing oxygen, or that are intended to be used in oxygen-enriched atmospheres, shall comply with the appropriate provisions of Chapter 8, "Gas Equipment," and Chapter 19, "Hyperbaric Facilities," in addition to all applicable provisions of this chapter.

9-2.1.7.3 Inhalation Anesthetizing Locations. Electric appliances used in inhalation anesthetizing locations shall comply with the provisions of Chapter 7, "Electrical Equipment," and 12-4.1, in addition to all applicable provisions of this chapter.

9-2.1.8 Instruction Manuals and Labels.

9-2.1.8.1 Manuals. The manufacturer of the appliance shall furnish operator's, maintenance, and repair manuals with all units. These manuals shall include operating instructions, maintenance details, and testing procedures.

The manuals shall include the following where applicable:

- (a) Illustrations that show location of controls
- (b) Explanation of the function of each control

- (c) Illustrations of proper connection to the patient and other equipment
- (d) Step-by-step procedures for proper use of the appliance
- (e) Safety considerations in application and in servicing
- (f) Difficulties that might be encountered, and care to be taken if the appliance is used on a patient simultaneously with other electric appliances
- (g) Schematics, wiring diagrams, mechanical layouts, parts lists, and other pertinent data for the appliance as shipped
- (h) Functional description of the circuit
 - (i) Electrical supply requirements (volts, frequency, amperes, and watts), heat dissipation, weight, dimensions, output current, output voltage, and other pertinent data
 - (j) The limits of electrical supply variations—performance specifications of the appliance shall be given for the applicable limits of electrical supply variations.
- (k) Technical performance specifications including design levels of leakage current
- (l) Instructions for unpacking (readily available upon opening), inspecting, installing, adjusting, and aligning
- (m) Comprehensive preventive and corrective maintenance and repair procedures

Where appropriate, the information itemized shall be permitted to be supplied in the form of a separate operating manual and a separate maintenance manual, except that the separate maintenance manual shall also include essentially all the information included in the operating manual.

9-2.1.8.2 Operating Instructions on Appliances. Condensed operating instructions shall be visibly and permanently attached to, or displayed on, any appliance that is intended to be used in emergency situations and that could result in injury or death to the operator or patient if improperly used.

9-2.1.8.3 Labeling. The manufacturer shall furnish, for all appliances, labels that are readily visible and legible and that remain so after being in service for the expected life of the appliance under hospital service and cleaning conditions. Controls and indicators shall be labeled to indicate their function. When appropriate, appliances shall be labeled with precautionary statements. All appliances shall be labeled with model numbers, date of manufacture, manufacturer's name, and the electrical ratings including voltage, frequency, current, and/or wattage of the device. Date of manufacture shall be permitted to be a code, if its interpretation is provided to the user. Appliances shall be labeled to indicate if they (1) are listed for use as medical equipment and (2) have isolated patient leads. Appliances intended for use in anesthetizing locations shall be labeled in an approved manner. (See 12-4.1.)

9-2.1.9 Additional Requirements for Special Appliances.

9-2.1.9.1 Signal Transmission Between Appliances.

(a)* *General.* Signal transmission lines from an appliance in a patient location to remote appliances shall employ a signal transmission system designed to prevent hazardous current flowing in the grounding interconnection of the appliances.

(b) *Outdoor Signal Transmission.* Outdoor signal transmission lines from appliances attached to patients shall be equipped with surge protection appropriate to the type of transmission line used. Such appliances or signal transmission

lines shall be designed to prevent a hazard to the patient from exposure of the lines to lightning, power contact, power induction, rise in ground potential, radio interference, and so forth.

9-2.1.9.2 Appliances Intended to Deliver Electrical Energy.

(a)* *Conditions for Meeting Safety Requirements.* Electrical-energy-delivering appliances shall conform to the leakage, grounding, and other requirements of this chapter when powered but not delivering energy.

(b) *Specific Requirements by Type of Device.*

1.* *Electrically Powered Transducers.* Exposed metal parts of these devices shall be considered electrodes and meet the applicable requirements of 9-2.1.13, Manufacturers' Tests for Safety of Patient-Care-Related Electrical Appliances. Connectors shall be designed to prevent inadvertent interchange of leads if interchange could constitute a hazard to the patient or operator.

2.* *Patient Impedance Measuring Devices.* For a particular application, the combination of frequency and current levels shall limit the applied current to the minimum necessary to achieve the medical purposes, but not to exceed the limits given in 9-2.1.13.5, Lead Leakage Current Tests and Limits.

Exception: The limits given in 9-2.1.13.5 shall be permitted to be exceeded if essential for the intended clinical function.

3.* *Electrotherapeutic Devices.* Appliances that require specific pulse forms or high power levels shall be designed to protect the operator and attendant personnel from accidental electric shock.

4.* *Electrosurgery.* Electrosurgical devices shall meet the requirements of 9-2.1.9.2(a), Conditions for Meeting Safety Requirements.

5.* *Cardiac Defibrillation.* Cardiac defibrillators shall be designed to protect the operator and attendant personnel from accidental electric shock.

9-2.1.9.3 Electrical Equipment in Oxygen-Enriched Atmospheres. Appliances or part(s) of an appliance or system (e.g., pillow speaker, remote control, pulse oximeter probe) to be used in the site of intentional expulsion shall comply with the requirements of this section. Those parts of an appliance or system not within oxygen delivery equipment, or not intended to be used in the site of intentional expulsion, shall not be required to comply with this section. Electrically powered equipment intended to be used within oxygen delivery equipment shall comply with (a), (b), (c) or (d) as listed below.

(a) Listed for use in oxygen-enriched atmospheres.

(b) Sealed so as to prevent an oxygen-enriched atmosphere from reaching electrical components. The sealing material shall be of the type that will still seal even after repeated exposure to water, oxygen, mechanical vibration, and heating from the external circuitry.

(c) Ventilated so as to limit the oxygen concentration surrounding electrical components to below 23.5 percent by volume.

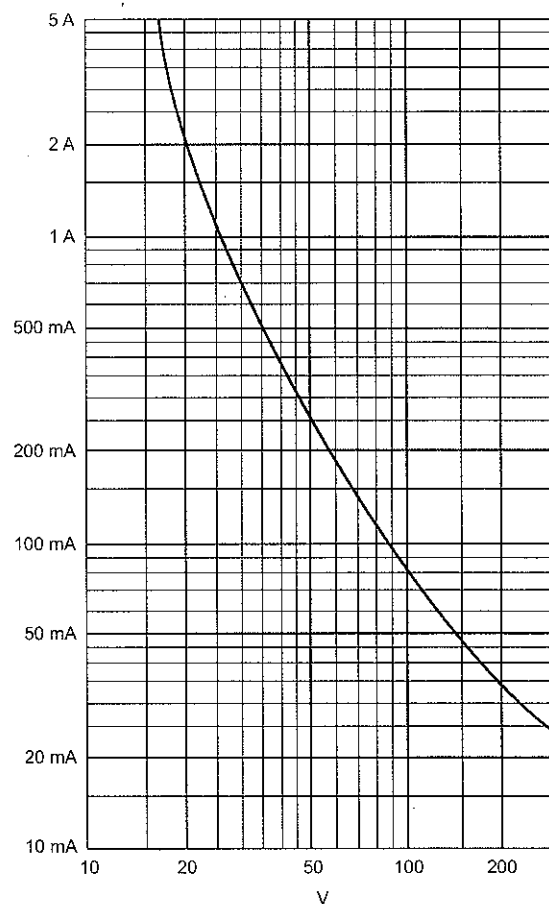


Figure 9-2.1.9.3(a) Resistance circuits ($L < 1$ mH). Minimum igniting currents, applicable to all circuits containing cadmium, zinc, or magnesium.

(d) Both of the following:

1. No hot surfaces over 573°F (300°C).

Exception: Small (less than 2-W) hermetically sealed heating elements such as light bulbs.

2. No exposed switching or sparking points of electrical energy that fall to the right of the curve for the appropriate type of circuit contained in Figures 9-2.1.9.3(a) through (f). The dc (or peak ac) open-circuit voltage and short-circuit current shall be used.

9-2.1.10 Low-Voltage Appliances and Appliances Not Connected to the Electric Power Distribution System.

9-2.1.10.1 General. Appliances and instruments operating from batteries or their equivalent or from an external source of low voltage or that are not connected to the electric power distribution system shall conform to all applicable requirements of 9-2.1, Patient-Care-Related Electrical Appliances. This shall include communication, signaling, entertainment, remote-control, and low-energy power systems.

Exception: Telephones.